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(54) Ultrasonic doppler synchronized cardiac electrotherapy device.

(57) A cardiac electrotherapy device comprises a Doppler measurement cardiac pacing lead within at least one Doppler measurement ultrasonic piezoelectric transducer means (55/57/58, 56/62/63) being arranged and mounted onto the said cardiac lead at the circumference thereof in a manner as to be able of generating an essential narrow directivity characteristic adjacent to the catheter body (50) in such a way as to prevent an intersection of the ultrasonic beam of said transducer means with said plastic body (50) in straight position of this body.

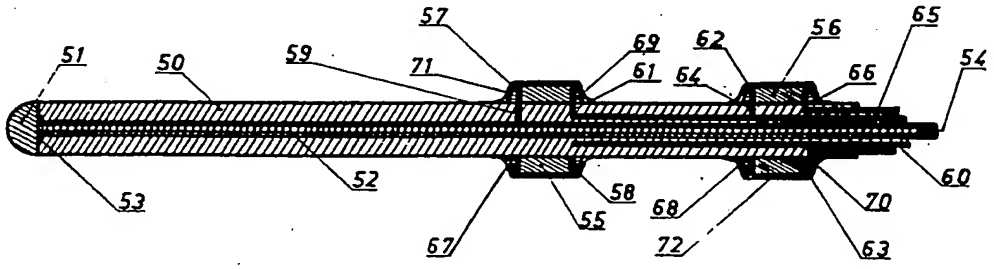

FIG. 4

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This invention relates to cardiac electrotherapy, particularly to measurement of blood flow characteristics within the heart and large blood vessels for the purpose of control of electrotherapy.

Ultrasonic measurement of blood flow has recently become an important noninvasive diagnostic method. Two methods have emerged as practical, i.e. the continuous wave (CW) and the pulsed (PW) Doppler systems. Very sophisticated and clinically useful systems have been developed such as described in the US-PS 4,790,322 enabling automatic measuring independent to direction of ultrasonic beam emission. The ultrasonic transmitter-receiver for blood velocity measurement was described in the US-PS 4,766,905 having improved noise reduction. Another system disclosed in the US-PS 4,771,789 calculates and displays acceleration of moving reflective member in organism. Flow imaging detector for blood velocity measurement, such as disclosed in the US-PS 4,790,323, weights samples of auto-correlation function with reliability criterion so electrical noise dominated samples can be weighted less. All these inventions enabled the perfect imaging of the blood flow in the echocardiographic scanner image. Nevertheless in some clinical applications more accuracy was necessary and therefore the ultrasonic invasive methods have been introduced. An apparatus with a catheter for ultrasonic examining of hollow organs was described in the US-PS 3,938,502. With continuing miniaturization of the apparatus the idea of measuring blood flow or other parameters with piezoelectric transducers mounted on catheters (cardiac or other) became feasible. The localization and visualization systems have been developed which enabled the ultrasonic guidance of invasive procedures. The ultrasonic needle tip localization system was disclosed in the US-PS 4,249,539. The ultrasonically marked catheters and cardiac pacing leads have been described in the US-PS 4,697,595 and in the US-PS 4,706,681 respectively.

A particular problem to be solved is the measurement of the blood flow characteristics within the heart and large blood vessels. The system disclosed in the US-PS 4,319,580 was developed to detect air emboli in the blood by using a cylindrical transducer for the detection. This approach was adequate for strongly reflective objects such as emboli and for the specified task of essentially only detecting them. The approach, however, does not yield a possibility to measure the flow characteristics as needed for pacemaker control and a development yielding such a possibility is the purpose of the present invention.

Along similar lines there have been developed devices for measurement and control of large vessel blood flow estimation and cardiac output measurement as per US-PS 4,771,788 and US-PS 4,802,490. Apart form its use as a Doppler transducer, the device described in the US-PS 4,802,490 is from the ultrasonic point of view equal to the devices described in the US-PS 4,706,681 and 4,697,595 although it has an additional flow restriction device which is immaterial in the comparison of prior art for the present application. The requirement and property added in the present invention is the ultrasound beam shaping and tilting device which unlike in the said inventions positively controls the direction of Doppler measurements with an added accuracy and reliability. The device described in the US-PS 4,771,788 has basically the same ability to measure the flow by means of ultrasound, but is not suitable for implantation in the human body as a part of an electrotherapy system. This is so because it requires and additional support wire, which for different purposes may be helpful, but rules the method out for the afore mentioned purposes.

Physiologic cardiac pacing is very important on temporary as well on permanent basis. Temporary pacing is usually applied either after cardiac surgery or during myocardial infarction because of the transient conduction disturbance of arrhythmia. Patients in rest have significantly improved cardiac output when ventricular contraction is synchronous with atrial filling of ventricles. This is very important for faster recovery after surgery of myocardial infarction. Furthermore, some arrhythmias like supraventricular tachycardias and extrasystolies may be prevented by means of physiologic pacing.

Patients with chronic conduction and rhythm disturbance have to receive a permanent implantable pacing system. They also have a significant contribution of atria to the hemodynamic benefit. There are two basic modes of physiologic cardiac pacing: sequential and synchronous. The sequential atrio-ventricular pacing is used to restore normal atrio-ventricular relationships. In this mode an atrium and a ventricle are paced by twin stimuli separated by an appropriate physiologic interval. However the heart rate is controlled by the pacemaker programme and does not vary according to the physiological needs. The synchronous cardiac pacing approximates most closely to the normal cardiac rhythm. The spontaneous atrial electrogram (P-wave) is sensed by an electrode usually in contact with the atrial endocardium and this is used to trigger the ventricle after an appropriate preset delay. Because the atrial rhythm is paced by our natural pacemaker sinus-atrial node, the frequency varies naturally according to the body workload. Therefore the P-wave synchronous ventricular cardiac pacing is considered to be the most physiologic rate-responsive pacing.

There is a significant drawback of physiologic pacing systems which complicated the surgical

procedure in comparison with non-physiologic pacing. The physiologic pacing requires the implantation of two leads: one atrial and one ventricular. Modern dual-chamber pacemakers have the ability to switch from sequential to synchronous pacing and vice versa according to the atrial rhythm which is monitored in the atrial channel. If the patient has a normal function of the sinus node and atria, the atrial lead is only used to sense the atrial activity and the ventricular lead is used to sense the ventricular activity and to pace the ventricles. Because the sensing of atrial activity may be done by an electrode floating within the right atrial cavity, a lot of effort has been done to design a single pass lead for P-wave synchronous ventricular pacing comprising the atrial and ventricular electrode on the same lead. Such a system has been described in the US-PS 3,903,897. However, the atrial electrogram is having significantly lower amplitude when sensed by a floating electrode in comparison with an electrode having a direct contact with the atrial muscle. Therefore such systems have to comprise high sensitivity amplifier in the atrial channel. As a consequence, the high susceptibility on far fields appears, causing more likely occurrence of the various oversensing phenomena. Furthermore, many patients have low amplitude atrial electrogram and therefore the atrial undersensing is more frequent in such systems. The system described in the EP-B 0 311 019 monitors ventricular impedance continuously using electrode in ventricle without requiring additional sensing in the atrium. Detected impedance waveform can be used to trigger ventricular stimulus synchronously with atrial filling of ventricle.

Very important technical and clinical performance of P-wave synchronous pacemakers is the upper rate behavior. Maximum pacing rate of ventricles is limited and therefore the atrial rhythm tracking by the ventricles will happen within the specified frequency range. The maximum tracking rate has to be programmable parameter in order to tailor the pacing frequency range according to the patients needs. Those who suffer from angina pectoris and impaired ventricular function are not capable to tolerate high tracking rates, while those with healthy cardiac muscle can tolerate high rate ventricular pacing. The synchronous pacing can be impaired by the atrial undulation and fibrillation when pacemaker sustains the maximum tracking rate during high atrial pathologic rhythm. Therefore even the intermittent atrial fibrillation is the contraindication for synchronous pacing. Patients suffering form intermittent atrial fibrillation would benefit a lot from a pacemaker comprising reliable atrial fibrillation detector and which could switch from synchronous to rate responsive pacing in the case of atrial fibrillation occurrence and vice versa, switch back to the synchronous mode upon the fibrillation termination. It would be very important that a pacemaker could monitor the ventricular performance and adapt the maximum tracking rate in such a way as to prevent angina and high-rate induced ischemia. It would be also important that a pacemaker could discriminate premature ventricular contractions with compensatory pause from those without the compensatory pause. Especially in anti-tachycardia devices it would be important that a pacemaker could discriminate the sinus tachycardia from pathologic tachycardia. As far it is known to the inventors such a pacemaker was not described in the prior art.

It is an object of the present invention to provide an ultrasonic Doppler synchronized cardiac electrotherapy device which positively controls the direction of Doppler measurement with high accuracy and reliability. Any arbitrary movements of the transducer means within the blood vessel or a chamber of the heart shall be restricted and any floating of the pacing electrode shall be avoidable.

It is a further object of the present invention to provide a pacemaker which will, in normal atrial rhythm, act in a synchronous mode and maintain atrio-ventricular synchronism, yet with the need for implantation of a single lead.

It is a further object of the present invention to provide a pacemaker comprising a sensor for rate responsive ventricular pacing.

It is a further object of the present invention to provide a pacemaker comprising a reliable means for for atrial fibrillation detection and which will maintain the rate responsive pacing while the atrial fibrillation is sustained.

It is another object of the present invention to provide a cardiac pacemaker which will monitor the right ventricular filling dynamics in order to estimate the ventricular muscle performance, and which will automatically reprogram the maximum tracking rate in such a way as to prevent the angina pectoris and high-rate induced myocardial ischemia.

It is a special object of the present invention to provide a pacemaker capable to detect premature ventricular contractions without as well as with compensatory pause.

It is another special object of this invention to provide a pacemaker capable to confirm the ventricular capture.

It is also a special object of this invention to provide a pacemaker capable to discriminate the sinus tachycardia from the pathologic tachycardia. The invention is characterized by the features of claim 1. Further aspects of the invention are specified in the remaining claims.

In carrying out the invention, the blood flow along a blood vessel or within the heart is mon-

itored with a Doppler system using piezoelectric transducers mounted in a special way on a cardiac pacing lead.

Preferable the flow waveform through the tricuspid valve is used for synchronization and control of ventricular cardiac pacing.

These and other objects will be more readily understood by reference to the following description and accompanying drawing in which

Fig. 1 is a perspective view of an unipolar cardiac pacing lead comprising axially polarized piezoelectric transducer for pulsed wave flow measurement, showing the distal part of the lead,

Fig. 2 is a perspective view of an unipolar cardiac pacing lead comprising a pair of axially polarized transducers for continuous wave flow measurement, showing the distal part of the lead,

Fig. 3 is a detailed axial cross-sectional view of the segment of pacing leads from Fig. 1 and 2 disclosing the part of lead where the flow measurement transducer is fixed,

Fig. 4 is an axial cross-sectional view of the distal part of pacing lead from Fig. 2,

Fig. 5 is an axial cross-sectional view of the segment of unipolar cardiac pacing lead comprising radially polarized transducers for continuous wave flow measurement,

Fig. 6 is a view along the distal part of the lead such as shown in Fig. 5 disclosing the principle of ultrasonic radiation,

Fig. 7 is a cross-sectional four chamber view of the human heart showing approximately the anatomic structure and a cardiac pacing lead from Fig. 1 and 3 implanted in the right heart,

Fig. 8 is an illustration of a typical waveform of the pulsed Doppler blood flow measurement through the tricuspid valve, relative to the electrocardiogram,

Fig. 9 is a simplified block diagram of a pacemaker comprising the pulse Doppler flow measurement circuit,

Fig. 10 is a flow-chart illustrating the logical function of a pacemaker from Fig. 9,

Fig. 11 is a detailed axial cross-sectional view of the segment of another pacing lead, disclosing the part of lead where a transducer made from a piezo film is fixed,

Fig. 12 is a detailed axial cross-sectional view of the segment of a further pacing lead, wherein pairs of plate-like transducers for velocity measurement are mounted at the circumference of the lead,

Fig. 13 is the transversal cross-section F-F as indicated in Fig. 12,

Fig. 14 is a side-view of the lead of Fig. 12 and 13 and

Fig. 15 illustrates the situation of Fig. 14 rotated by an angle of 90°.

In the embodiment of example 1 a pulsed wave flow measurement cardiac pacing lead consists of a plastic body 10 having a pacing electrode 11 on the tip. A pulsed wave flow measurement piezoelectric transducer 12 of cylindric form is built into the lead and fixed at its surface at a distance from the tip electrode. The distance is such that, in normal operation, the transducer 12 is positioned near to and proximal to the tricuspid heart valve. There is a plastic ultrasound lens 13 distally by the transducer which determines the direction of ultrasound transmission and reception. A reflective or absorptive backing 14 is fixed proximally by the transducer. The transducer is of a cylindrical form poled lengthwise and with electrodes on its top an bottom. In this way the ultrasound directivity characteristics are directed along the catheter. This particular property makes it virtually insensitive to flows in other directions than the axial. At the proximal end of the lead, which is not shown, there is a connector system for the connection of the lead to the electronic circuits.

In the embodiment of example 2 a continuous wave flow measurement cardiac pacing lead consists of a plastic body 20 having a pacing electrode 21 on the tip. There are two piezoelectric transducers 22 and 23 mounted coaxially with the lead at a distance from the tip. The distance is such as to position the transducers 22 and 23 in the vicinity of the tricuspid heart valve. The transducers 22 and 23 are of a ring or cylindric form, with electrodes at their top and bottom (not shown) connected via built in lead conductors (not shown) to the lead connector (not shown) at the proximal end of the lead which is not shown. The plastic ultrasound lenses 24 and 25, as well as the absorptive or reflective backings 26 and 27 control the direction of ultrasound transmission and reception, respectively.

In the embodiment of Fig. 3 there is disclosed a detailed axial cross-section of the lead and the flow measurement transducer either from the lead of Fig. 1 or from the distal transducer of the lead according to Fig. 2. Within the plastic body 30 there is a lead conductor 31 having a stylet channel 32 which connects the pacing electrode at the distal end (not shown) with the connector at the

proximal end (not shown) of the lead. The cylindrical piezoelectric transducer 33, mounted coaxially on the plastic body 30, has two electrodes 34 and 35 which are co-fired at the proximal and distal end of the transducer in such a way as to pole the transducer axially. The transducer electrode 34 is electrically connected with the pacing lead conductor 31 by means of the connection bridge 36. The transducer electrode 35 is electrically connected with another lead conductor 37 by means of another connection bridge 38. An ultrasonic lens 39 is fitted and glued by the transducer. The lens 39 is of the form of a tapered ring and represents an essentially conical ultrasonic lens. At the end opposite to the lens of the transducer there is a backing 40 glued onto the electrode 35. The backing 40 is built of either an air equivalent material such as expanded plastic or of an ultrasound absorbing material such as synthetic resin filled with metal powder. This backing is of such a tapered form that it does not obstruct the indwelling procedure. The lens 39, the transducer 33 and the backing 40 are covered with a thin sheath 41 of electrically insulating material not thicker than 5% of the ultrasound wavelength used.

The disclosed lead assembly comprises helically wounded coaxial lead conductors with a stylet channel which is the technology used in leads for permanent implantation. Simpler design is possible for temporary cardiac leads using ordinary insulated copper wires in a plastic tube. The plastic body may consist of multiple insulation sheaths i.e. plastic tubes between and over the lead conductors.

In the embodiment of Fig. 4 the distal part of the continuous wave flow measurement pacing lead consists of a plastic body 50 having an electrode 51 on its tip which is electrically connected to the inner lead conductor 52 by means of either conductive gluing or soldering member 53. The inner lead conductor 52 has a stylet channel 54 and on the proximal part of the lead (not shown) it is terminated with connector pin (not shown) on the connector assembly (not shown). Proximally from the tip there is a flow measurement assembly comprising two cylindric piezoelectric transducers 55 and 56 which are mounted coaxially with the plastic body 50. Transducer 55 comprises co-fired electrodes 57 and 58 which pole the transducer 55 axially. The electrode 57 is electrically connected to the inner lead conductor 52 by means of conductive bridge 59. In the same manner, the electrode 58 is connected to the middle coaxial lead conductor 60 by means of the conductive bridge 61. In disclosed example, transducer 55 is electrically connected to the electronic circuits (not shown) through lead conductors 52 and 60 by means of said connector assembly (not shown) at the proximal end of the lead (not shown). Transducer 56 comprises co-fired electrodes 62 and 63 which pole the transducer 56 also axially. The electrode 62 is electrically connected to the middle lead conductor 60 by means of the conductive bridge 64. In the same manner, the electrode 63 is connected to the outer lead conductor 65 by means of the conductive bridge 66. In disclosed example, transducer 56 is electrically connected to the electronic circuits (not shown) through lead conductors 60 and 65 by means of the said connector assembly (not shown) at the proximal end of the lead (not shown). Ultrasonic lenses 67 and 68 are fitted to the transducer electrodes 57 and 62, respectively, and glued. The lenses 67 and 68 are of the form of tapered rings and represent essentially conical ultrasonic lenses. At the opposite end of the transducers 55 and 56, backings 69 and 70 are fitted to the transducer electrodes 58 and 63, and glued. The backings are made of either an air equivalent material such as expanded plastic or of an ultrasound absorbing material such as synthetic resin filled with metal powder. Backings are of such a tapered form that they do not obstruct the indwelling procedure. The distance between transducers 55 and 56 is much larger than the ultrasound wavelength within the body tissues. The distance of the transducers 55 and 56 from the lead tip and electrode 51 is such as to enable the continuous wave flow measurement through the tricuspid valve while the electrode 51 is positioned in the apex of the right ventricle. Transducers 55 and 56, lenses 67 and 68, as well as backings 69 and 70 are covered with electrically insulating plastic sheets 71 and 72 respectively, which are not thicker than 5% of the ultrasound wavelength used. Disclosed lead assembly comprises helically wounded coaxial lead conductors and a stylet channel which a typical design for permanent leads. Simpler design is possible using standard insulated copper wires in a plastic tube which is typical design for disposable temporary pacing leads.

In the embodiment of Fig. 5 there is disclosed a flow measurement assembly of the continuous wave flow measurement pacing lead. The lead comprises a plastic body 80 and piezoelectric transducers 81 and 82 which are embedded within the body 80. Transducer 81 is poled radially by means of electrodes 83 and 84, while the transducer 82 is poled radially by means of electrodes 85 and 86. Transducers 81 and 82 can be made in cylindrical form, or can be made as a folded piezoelectric plastic foil (PVDF type). The inner lead conductor 87 having a stylet channel 88 is terminated on its distal end with a pacing electrode (not shown) and on its proximal end with a connector pin (not shown) as part of connector assembly (not shown).

Conductor 87 is electrically connected with electrode 83 by means of a conductive bridge 89. The middle coaxial lead conductor 90 is electrically connected to the electrode 84 by means of conductive bridge 91 as well as to the electrode 86 by means of a conductive bridge 92. The outer coaxial lead conductor 93 is electrically connected to the electrode 85 by means of a conductive bridge 94. In such a way of electrical connections transducer 81 is connected to the external electronic circuits (not shown) through coaxial lead conductors 87 and 90 by means of said connector assembly (not shown) at the proximal end (not shown) of the lead. In the same manner the transducer 82 is connected to the said external electronic circuits through coaxial lead conductors 90 and 93 by means of said connector assembly. The beam tilt needed for appropriate blood velocity measurement is achieved by using ultrasound lenses 95 and 96, as well as by means of reflective coatings 97 and 98.

In the embodiment of Fig. 6 there is a side view of the distal part of the continuous wave flow measurement pacing lead similar to that from Fig. 5 illustrating the ultrasonic beam tilt. The lead comprises a plastic body 100 having a pacing electrode 101 on the tip. The ultrasonic lenses 102 and 103 as well as reflective coatings 104 and 105 direct the sensitivity of transducers in such a way as it is illustrated by means of dashed lines which designate the geometric shape of the axial cross-section of the ultrasonic beams. The ultrasound beams of both transducers are axially symmetric having geometric shapes of a top-cut hollow cone, in such a way as to avoid the intersection of ultrasonic beams with the lead itself. The geometric intersection of these two beams is a sensitivity volume axially symmetric with the axis of the lead, s axial cross-section 106 being two rhomboids. he blood velocity is measured within the sensitivity volume. Disclosed physical principle of the ultrasonic beams tilt and sensitivity volume as a beam intersection may be generalized for all continuous wave flow measurement leads, also for the lead from Fig. 2 and 4. The same geometrical shape of the ultrasonic beam is achieved by means of transducer assembly from Fig. 3 and lead from Fig. 1 for use with PW Doppler systems. Furthermore, it is very important for CW as well as for PW Doppler lead that the ultrasonic beam is hollow in such a way as to prevent the intersection of beam with the lead itself.

In the embodiment of Fig. 7 the pulsed wave flow measurement pacing lead is shown within the anatomic structures of the human heart. The heart is disclosed in the four chamber cross-section and the myocardial cross-section is visible of the left-ventricular wall 110, the right-ventricular wall 111, the interventricular septum 112, the left-atrial wall 113 and the right-atrial wall 114. Two chambers of the left heart, left ventricle 115 and left atrium 116 are separated by the mitral valve 117. The left ventricular outflow tract consists of the aortic valve 118 and aorta 119. A cardiac pacing lead 120, such as disclosed in Fig. 1, is implanted through the vena cava superior 121 and the right atrium 122 in the right ventricle 123, with its pacing electrode 124 located in the apex of the right ventricle. In the low right-atrial region above the tricuspid valve 125, the lead 120 comprises a flow measurement assembly 126 such as disclosed in Fig. 3. Dashed lines emanating from the flow measurement assembly 126 designate the cross-section of the axially symmetric ultrasonic beam. The ultrasonic beam is directed in such a way as to enable the pulsed wave measurement of the blood flow through the tricuspid valve 125. Because the lead is bent in rhythm of cardiac contractions, it is important that the ultrasonic beam does not intersect the lead which could provoke the distortion in the tricuspid flow pattern caused by movements of the lead.

In the embodiment of Fig. 8 and example of the electrocardiogram and corresponding pulsed wave Doppler waveform is disclosed. P waves, QRS complexes and T waves are designated illustrating a normal ECG. The envelope of the pulsed wave Doppler waveform through the tricuspid valve is disclosed under the ECG in exact time correlation to the ECG. Important timing intervals are designated like Doppler refractory period DRP, Doppler measurement interval DMI and atrio-ventricular interval. After the repolarization of the heart which caused the T wave 150, the relaxation of the heart muscle causes the early diastolic filling wave 151 having the peak blood velocity E. The following atrial depolarization causes the P wave 152 and corresponding atrial muscle contraction which pumps additional blood quantity producing the blood flow wave 153 having peak velocity A.

The ratio of peak velocities E/A is a hemodynamic parameter showing the cardiac muscle performance. The same Doppler waveform is obtained when measuring the mitral valve flow where peak velocities are having greater values (in order of 1 m/s) in comparison with tricuspid valve velocities being half slower. Another hemodynamic parameter being used in clinical practice is the ratio of the time integrated wave E and the time integrated wave A. The example is given for the healthy human heart, but pathologic conditions may disturb this relations. This is used in this invention for diagnostic purposes. First of all, synchronized pacing is obtained in this invention by means of sensing the Doppler A wave and synchronizing the ventricular pacing with it, and not

with the endocardial P wave as it is done in conventional VDD pacing systems. This is illustrated in last complex where following A-wave 154 is sensed and the atrioventricular interval 155 is initiated (shown as a black bar). At the end of the A-V interval the pacing impulse I is generated producing the paced R-wave 156. It is obvious that A-V intervals in this system are much shorter than in systems which sense the atrial electrogram. In the case of atrial fibrillation Doppler A waves disappear and this is used for atrial fibrillation detection. In the case of severe ventricular arrhythmia like ventricular tachycardia and fibrillation, E waves disappear because the missing ventricular contraction cause missing ventricular relaxation. This is used for reliable life threatening arrhythmias detection. Any ischemic episode like pacing induced high rate ischemia will change the ratio of peak velocities as well as the ratio of time integrals. This is used for physiologic maximum tracking rate response to prevent angina pectoris. The E/A ratio is significantly decreased in the case of ventricular premature contraction without the compensatory pause. Circulatory catecholamines directly influence the interval between the QRS complex and the corresponding following Doppler E wave as well as they influence the rate of diastolic filling. Therefore the sensors (data) for rate responsive pacing are available in this system.

In the embodiment of Fig. 9 a generalized block diagram of a microprocessor controlled unipolar pacemaker is disclosed. Microprocessor 160 comprises a memory 161 where various data are kept in registers and counters generated by the software. Crystal oscillator 162 is producing exact time base and reed switch 163 may produce various functions known in the art. The implantable unit must be programmable by means of an external programmer and various telemetric functions are desirable. These functions are obtained by the programming and telemetry circuit 164 and radiofrequency communications circuit 165 with antenna. The output pacing circuit 166 comprises a programmable pulse generator, voltage double and protection circuit as it is known in the art. The programmable gain bandpass filter-amplifier 167 senses the endocardial ventricular signal picked-up by the electrode during spontaneous ventricular heart beat. Doppler circuit 168 detects and measures the blood flow and the analog to digital converter circuit 169 prepares the envelope of Doppler waveform for digital processing. Positive pole of pulse generator in circuit 166 and one pole of sensing amplifier 167 is connected to the pacemaker can 170. Negative pole of the pulse generator in circuit 166 and another pole of the sensing amplifier 167 is connected to the pin 171 of a bipolar connector assembly. Pin 171 is electrically connected to the active pacing electrode in the ventricle and to the ultrasonic transducer when the lead such as disclosed in Fig. 1 and 3 is coupled to the connector assembly. Another terminal of Doppler circuit 168 is connected to the pin 172 of a bipolar connector assembly being connected to the ultrasonic transducer of the lead such as described in Fig. 1 and 3. Disclosed system may have unipolar pacing and sensing function through the pacemaker can 170 and connector pin 171, as well as Doppler measurements through the connector pins 171 and 172. The Doppler circuit may be designated to operate in the PW mode or in the CW mode. For the PW mode one can use lower frequencies (down to 2 MHz) with the range gate set to near distance (up to 1.5 cm). In the CW mode the system operates at frequencies above 5 MHz, preferably at more than 8 MHz reducing the effective range to the necessary value. The data are measured at characteristic phases of cardiac cycle, i.e. in diastole, thereby saving energy from the pacemaker power source. The data collected in this way are fed into the pacemaker microprocessor and the data are then used for controlling the pacemaker. The Doppler electronic circuit can measure blood flow velocity using Doppler effect and to process the data to yield pulsatility and flow figures for pacemaker control. It can also measure the peak velocity as well as the time integral of the Doppler flow waveform envelope. Disclosed system comprises the connector assembly which is intended for use with pulsed wave Doppler lead for unipolar pacing. More complicated connector must be used in continuous wave system as well as in bipolar pacing system. Disclosed system can be incorporated in the implantable defibrillator-cardioverter as a pacing back-up system as well as a reliable system for fibrillation detection.

In the embodiment of Fig. 10, a generalized flow-chart discloses one of many possible modes how the microprocessor polls various circuits in order to logically connect the function of Doppler blood flow measurement and cardiac pacing. Other possible functions of a microprocessor such as tachycardia detection algorhythm, electromagnetic interference response, programming, telemetry interrogation and many other basic functions are not shown because these are well known in the art and are not the subject of this application. Sensing 200 of the spontaneous R-wave starts the routine and stops 201 the Doppler measurement interval DMI which is the time while the Doppler circuit is enabled for detection and measurement. Logical diagram connector is designated by 202 leading to the triggering 203 of the pacing impulse. In this example the rate responsive sensor is the QE interval which is the time interval from either the paced or sensed QRS complex to the correspond-

ing Doppler E wave. Therefore the measurement of this interval is started 204 by resetting the counter "RR". The Doppler circuit is enabled after a certain delay from the QRS complex, which is called Doppler refractory period DRP. The DRP duration depends on the heart rate and becomes shorter as the heart rate increase and vice versa. Therefore the heart rate is read 205 from the memory register "HR" and the DRP is calculated 206 according to the predetermined relation. This calculation may be in units of the "RR" counter and upon the DRP termination 209 the DMI is started 208. Microprocessor waits 209 for the occurrence of the E wave as long as is the programmed escape interval 210. Logical diagram connectors are designated by 211, 212 and 213. Any first Doppler wave will be assigned as an E wave and upon the occurrence 211 several actions will be initiated 213. The counter "RR" is stopped 214, now containing the QE interval duration. The counter "EE" is also stopped 215, now containing the interval between the former and the latter E wave, which is the numerical inverse of the actual heart rate. Doppler circuit measures 216 the peak blood flow velocity and stores its value in the memory register "E". The word in counter "EE" is read 217 and stored in a "First In Last Out" (FILO) type memory register, and the counter "EE" is reset 218 starting to measure the next E to E wave interval. The DRP is calculated 206 according to the average heart rate during the last several heart beats. Therefore the content of FILO memory register is averaged 219 and the result is stored in the memory register "HR". The capacity of FILO i.e. the number of FILO register words is equal to the number of last beat to beat intervals which are averaged for the average heart rate i.e. the content of register "HR". Microprocessor checks if the heart beat is with or without compensatory pause thus enabling to classify the premature ventricular contractions (PVCs) without the compensatory pause. This kind of PVCs produce significantly lower peak velocity of the early ventricular filling in comparison with the normal beat and PVCs with compensatory pause. Therefore the preprogrammed critical peak velocity Ec is read 220 from the memory and compared 221 with the measured peak velocity stored in register "E". If there was a decrease of the rate of early diastolic filling, the beat is considered to be a PVC without compensatory pause and the memory register "PVC" is incremented 222. The "PVC" memory register keeps the number of PVCs for later interrogation by the programmer for the diagnostic purpose. The software routine may now enter the waiting loop for the second Doppler wave 223 which may last till the end of the programmed escape interval 224. The second wave is considered to be the atrial filling A-wave. If the A-wave occurs, the software will continue to the synchronized pacing routine 225. If the A-wave is missing, the microprocessor considers that the atrial fibrillation occurred and the rate responsive pacing routine will proceed 226.

Logical diagram connectors are designated by 225, 226, 227 and 239.

The routine continues 227 with the measuring 228 of the peak velocity which will be stored in the memory register "A". The preprogrammed value of atrio-ventricular delay is read 229 from the memory and the microprocessor initiates the A-V delay 230. In the meantime the DMI is stopped 231 because there is no further Doppler wave expected. The content of memory register "E" is divided by the content of memory register "A" 232 in order to obtain the ratio of peak velocities of early diastolic and atrial filling. The same ratio of the former heart beat is read 233 from the memory register Eo/Ao. If the E/A ratio of the latter heart beat is significantly smaller 235 from the E/A ratio of the former heart beat, this means that the high rate ischemia is provoked and the angina pectoris may occur. The preprogrammed constant K1, read 234 from the memory, determines what is the significant change of the E/A ratio. In the case of high pacing rate ischemia, the A-V delay will be prolonged 236 in order to provoke Wenckebach tracking rate response. It is known from the art that other maximum tracking rate responses are possible like 2:1 block as well as the fallback rate pacing. If there is no change in E/A ratio the value of latter E/A ratio is stored 237 in the memory register Eo/Ao for the future comparison with the next heart beat. The A-V delay waiting loop is entered 238 and the pacing pulse will be generated 239, 202 at the end. In the case of atrial fibrillation 226, the pacemaker will be programmed 240 to the rate of responsive mode. The DMI is stopped 241 and the preprogrammed constant K2 is read 242 from the memory. Peak early diastolic velocities are read 243 from the register "Eo" for the former heart beat and from the register "E" for the latter heart beat. The high rate pacing induced ischemia will be always preceded by the drop of the early diastolic filling velocity. Therefore the protection algorhythm from high rates especially for patients with angina pectoris must be incorporated. The constant K2 determines the amount of beat to beat change of the peak velocity E. If the velocity E of the latter beat is significantly lower 244 than the velocity Eo of the former beat, the escape interval i.e. the pacing interval in rate responsive mode must be increased 245. The latter peak velocity E is stored 246 in register Eo for the future comparison with the next beat peak velocity. After that the pacing impulse may be generated 247. If there is no significant change 244 in peak velocity, the value E is stored 248 in register "Eo" for future comparison with

next beat peak velocity. The programmed rate responsive slope function is read 249 from the memory and according to the rate responsiveness sensor value stored in the counter "RR" 250, the new escape interval is calculated 251 and the pacing impulse is generated 252.

If there had been no first wave detected 209 and the escape interval was completed 212, the DMI is stopped 254. The microprocessor "knows" whether the expected Doppler wave had to be the consequence of the paced or the sensed beat. If this was a sensed beat 255, the flag which is influenced by the ventricular tachycardia and fibrillation detection algorhythms is read 256. If the fibrillation or ventricular tachycardia was detected 257,it is the life threatening arrhythmia and the anti-tachycardia subroutine is started 258 which may be defibrillation in implantable defibrillator or any other kind of anti-tachy therapy with an implantable device. If there was not tachycardia detected 257, the missing Doppler wave may have been caused by the lack of Doppler circuit sensitivity. Therefore the Doppler circuit sensitivity is increased 259. If this was a paced beat 255, the missing Doppler wave may have been caused by the loss of capture. Therefore the pacing output energy is reprogrammed to the higher step 260 and the pacing pulse is generated 261. Logic diagram connectors are designated by 240, 247, 252, 253 and 261. Disclosed logic diagram illustrates the function of a pacemaker only for the example of basic idea. The function of described invention in an external temporary pacemaker and in an implantable defibrillator was not particularly disclosed because the basic principle is the same with appropriate modifications as it is known in the art. For instance, there is no Figure in this disclosure which shows the intracardiac spring lead for implantable defibrillator, but it is obvious that Doppler transducers may be incorporated in such a lead keeping the right design rules in mind.

In the embodiment of Fig. 11 there is disclosed a detailed axial cross-section of the lead and the flow measurement transducer made of piezo film, either from the lead from Fig. 1 or from the distal transducer of the lead from Fig. 2. Within the plastic body 280 there is a lead conductor 281 having a stylet channel 282 which connects the pacing electrode at the distal end (not shown) with the connector at the proximal end (not shown) of the lead. The piezoelectric transducer 283 made of material such as Kynar Piezo Film (Penwalt Corp.), mounted coaxially on the plastic body 280, has two electrodes 284 and 285 i.e. thin metallized layers. The transducer electrode 284 is electrically connected with the pacing lead conductor 281 by means of the connection wire 286 and electrical joints 287 and 288. The transducer electrode 285 is electrically connected with another lead conductor 289 by means of another connection wire 290 and electrical joints 291 and 292. An ultrasonic lens 293 i fitted and glued by the transducer. The lens 293 is of the form of a tapered ring and represents an essentially conical ultrasonic lens. At the end opposite to the lens of the transducer there is a backing 294 glued onto the electrode 284. The backing 294 is built of either an air equivalent material such as expanded plastic or of an ultrasound absorbing material such as synthetic resin filled with metal powder. This backing is of such a tapered form that it does not obstruct the indwelling procedure. The lens 293, the transducer 283 and the backing 294 are covered with a thin sheath 295 of electrically insulating material not thicker than 5% of the ultrasound wavelength used.

The disclosed lead assembly comprises helically wounded coaxial lead conductors with a stylet channel which is the technology used in leads for permanent implantation. Simpler design is possible for temporary cardiac leads using ordinary insulated copper wires in a plastic tube. The plastic body may consist of multiple insulation sheaths i.e. plastic tubes between and over the lead conductors.

Another embodiment of the Doppler measurement device mounted at the point of interest on a cardiac pacing lead is the example comprising plate transducers. The said transducers are mounted on a tilted backing made of very ultrasound reflective material. The transducers are pairwise tilted out of the axial symmetry direction so that their directivities intersect, thus creating two sensitive volumes for continuous wave Doppler measurements. Unlike axially symmetric ultrasound sensitive volumes described above, this embodiment has two distinct sensitive volumes positioned at 180° across the catheter axis. The design, applicable for temporary pacing leads, is illustrated in Fig. 12 to 15.

Fig. 12 is an axial cross-section through a bipolar pacing lead comprising plate transducers for velocity measurement, mounted at an appropriate distance from the lead tip. The lead comprises:

- a plastic hollow catheter body 301 within which there are pacing-sensing lead conductors 302 and 303 which are electrically connected to the corresponding electrodes (not shown) at their distal end, and to the corresponding connector pins (not shown) at their proximal end,
- a backing 304 made of air equivalent material (hard expanded plastic) in form of a double truncated cone,
- a multitude of plate piezoelectric transducers 305 and 306 glued to a surface of the back-

ing 304, the transducers having thin metallized layers which are transducer electrodes 310, 311, 312, 313,

- additional two piezoelectric plate transducers (not shown) to achieve circular symmetry,
- additional lead conductor 326 for connection of transducers, said conductor being bifurcated in two conductors 318 and 328,
- additional lead conductor 327 for connection of transducers, said conductor being bifurcated in two conductors 320 and 329.

The connection conductor 318 is conductively glued or soldered by means of electrical joint 314 to the transducer electrode 310, thus lead conductor 326 being the first pole of transducer 305. The connection conductor 328 is connected to the adjacent transducer (not shown) in the same manner and for the same purpose. The connection conductor 320 is conductively glued or soldered by means of electrical joint 316 to the transducer electrode 312, thus lead conductor 327 being the first pole of transducer 306. The connection conductor 319 is conductively glued or soldered by means of electrical joint 315 to the transducer electrode 311, as well as by means of electrical joint 324 to the lead conductor 303, thus lead conductor 303 being the second pole of transducer 305. The connection conductor 321 is conductively glued or soldered by means of electrical joint 317 to the transducer electrode 313, as well as by means of electrical joint 325 to the lead conductor 303, thus lead conductor 303 being the second pole of transducer 306.

Transducers assembly is covered by means of an insulating sheath (membrane) 330 of thickness less than 5% of the wavelength of the dominant used ultrasound frequency covering the whole device.

Fig. 13 is the transversal cross section F-F as indicated in Fig. 12. The device is shown without the insulating membrane 330. In this illustration one can see all the four plate transducers 305, 306, 405 and 506 having thin metallized layers 310, 312, 410 and 512 respectively. The opposite metallized layers cannot be seen from disclosed view. These transducers are arranged in transmitter-receiver pairs, i.e. 306 and 506 are a pair and 305 and 405 are a pair. The paired transducers are tilted towards each other as can be seen by the perspective view of the transducer plates. The connection conductor 329 is connected to the transducer electrode 410 by means of the electrical joint 414, thus conductor 327 being the first pole of transducer 405. The connection conductor 328 is connected to the transducer electrode 512 by means of the electrical joint 514, thus conductor 326 being the first pole of transducer 506. The connection conductor 521 is connected to the transducer 506 through another metallized layer (not shown) by means of the electrical joint 517, and to the lead conductor 303 by means of the electrical joint 525, thus conductor 303 being the second pole of the transducer 506. The connection conductor 419 is connected to the transducer 405 through another metallized layer (not shown) by means of the electrical joint 415, and to the lead conductor 303 by means of the electrical joint 424, thus conductor 303 being the second pole of the transducer 405. In disclosed wiring assembly the lead conductor 303 is common for all four transducers. If the transmitter circuit is connected to lead conductor 326 and the receiver circuit to lead conductor 327 (or vice versa), transducers 305 and 506 will be ultrasonic transmitters while transducers 306 and 405 will be ultrasonic receivers (or vice versa). The sideways tilt results in the overlapping of the directivity characteristics of the said pairs of transducers as it is shown in following figures. The perpendicular cross sections through the sensitivity areas at the level of section F-F are shown as shaded areas 601 and 602.

Fig. 14 is a perspective drawing of the side view of the lead from Fig. 12 and 13 without the covering insulation sheath 330 in order to illustrate the positions and tilts of the piezoelectric transducers 305 and 405 as well as the ultrasound directivity characteristics of the two transducers. The transducers are glued onto the said air-equivalent backing 304. Their metallized layer electrodes are conductively glued or soldered by means of electrical joints 314 and 414 to connection conductors 318 and 329 respectively. The connecting wires of other said transducers and the rest of the connecting wires of transducers 305 and 405 are not shown. The body of the catheter 301 holds all the measuring devices, but can induce clutter into the ultrasonic measurement beams 340 and 440. The beams are illustrated by their boundaries; boundaries 441 and 442 for transducer 405 and beam 440, and boundaries 341 and 342 for transducer 305 and beam 340. Directivity axis 343 is for transducer 305 and beam 340 as well as directivity axis 443 for transducer 405 and beam 440. The overlapping region between the beams 440 and 340 is indicated as well 600. When the two transducers 305 and 405 act as a Doppler transmitter-receiver combination the overlapping region 600 is the sensitive area of the blood flow velocity measurement. Disclosed boundaries are drawn for illustration only and they can be exactly defined as a surface of specified ultrasonic field intensity.

Fig. 15 illustrates the situation of Fig. 14 only shown from an angle by 90° around the catheter axis different. This illustration shows that, while there is an overlapping zone between pairs of transducers as shown in Fig. 14, there is a dead

zone of sensitivity at positions at 90° around the axis to the said sensitive area positions. Two opposite sensitivity volumes 600 and 603 are disclosed. The former is the geometrical intersection of ultrasonic beams of transducers 305 and 405, while the latter is the geometrical intersection of ultrasonic beams of transducers 506 and 306. Disclosed transducers assembly produces two ultrasonic sensitive volumes in order to obtain more reliable blood velocity measurement. However, simpler design is possible with only two transducers producing one sensitive volume.

While specific embodiments of present invention have been described, it should be understood that these embodiments are described for purposes of illustration only. The foregoing description is not intended in any way to limit the scope of the present invention. Rather is the intention that the scope of the invention be limited only as defined in the appended claims.

Claims

1. A cardiac electrotherapy device comprising a Doppler measurement cardiac pacing lead, electronic circuitry for cardiac electrotherapy and electronic circuitry for Doppler blood flow velocity measurement, timing and processing of the velocity data, wherein said Doppler measurement cardiac pacing lead comprises

   a plastic catheter body (10, 20, 30, 50, 80, 100, 120, 280, 301), lead conductors (31/37, 52/60/65, 87/90/93, 281/289, 327/303/326 and 302) and a pacing electrode (11, 21, 51, 101, 124),

   at least one Doppler measurement ultrasonic piezoelectric transducer means (12, 22/23, 33, 55/56, 81/82, 283, 305/306, 405/506), comprising transducer electrodes (34/35, 57/58, 62/63, 83/84, 85/86, 284/285, 310 to 313, 410, 512),

   said transducer means being arranged and mounted onto the said cardiac lead at the circumference thereof in a manner as to be able of generating an essential narrow directivity characteristic adjacent to the catheter body in such a way as to prevent an intersection of the ultrasonic beam of said transducer means with said plastic body in straight position of this body.

2. Device according to claim 1 wherein said transducer means has a shape of a hollow cylinder (12, 22, 23, 33, 55, 56), hollow cone, perforated disk (283) or foil, with said electrodes (34/35, 57/58, 62/63, 284/285) arranged at the ends thereof and

   is coaxially mounted onto the cardiac lead,

   and poled so as to generate a hollow conical directivity characteristic.

3. Device according to claim 1, wherein said transducer means has a shape of a hollow cylinder (81, 82) or hollow cone or folded piezoelectric plastic foil with said electrodes (83/84, 85/86) arranged along the inner and outer circumferential surfaces thereof and

   is coaxially mounted onto the cardiac lead so as to generate a hollow conical directivity characteristic.

4. Device according to claim 2 or 3, wherein two transducer means (22/23, 55/56, 81/82) are arranged, spaced apart from each other, whereby the directivity characteristics cross each other to form a sensitivity volume (106).

5. Device according to claim 1 wherein said transducer means (305, 306, 405, 506) comprises at least one pair of plate-like transducers (305/405), each having arranged said electrodes (310, 311, 410) on both sides, and

   that the paired transducers (305/405 and 306/506) are tilted towards each other so as to obtain a sensitivity area by an overlapping region (600 and 603) of their directivity characteristics.

6. Device according to any of claims 1 to 5, wherein said transducer means of said lead comprises a reflective or absorbing member (14, 26, 27, 40, 69, 70, 97, 98, 104, 105, 294, 304) mounted fixedly at one side of the transducer means in order to prevent the ultrasonic radiation in direction to the side of the transducer means where said reflective member is mounted.

7. Device according to any of claims 1 to 6, wherein said transducer means comprises an ultrasonic lens (13, 24, 25, 39, 67, 68, 95, 96, 102, 103, 293) mounted fixedly at one side of said transducer means (12, 22, 23, 33, 55, 56, 81, 82, 283) whereby the ultrasonic radiation is directed to the side of said transducer means where said lens is mounted.

8. Device according to claim 7, wherein said lens has a shape of a top-cut hollow cone which is coaxial with the lead axis, the lens being essentially of a tapered conical ring form.

9. Device according to any of claims 1 to 8, wherein said Doppler measurement cardiac pacing lead (120) comprises a connector assembly at its proximal end wherein said lead

conductors electrically connect pacing electrodes with corresponding pins (170, 171) of said connector assembly and transducer electrodes with corresponding pins (171, 172) of said connector assembly in such a way as to enable the electrical connection of said pacing electrodes with cardiac pacing electronic circuitry cited in claim 1 as well as the electrical connection of said transducer electrodes with Doppler electronic circuitry cited in claim 1 without interference between said transducers high frequency signal and said pacing electrodes signals.

10. Device according to any of claims 1 to 9, comprising means for a ventricular pacing synchronous with atrial contractions with the use of a single said lead (120) and means for a rate responsive pacing (166), wherein said means are controlled by means of processing (160, 168, 169) of the Doppler waveform of blood flow through a cardiac valve (125).

11. Device according to any of claims 1 to 10, comprising means for measurement of the blood velocity during determined time interval (DMI) synchronized with the ventricular electrical activity, said interval occurring with a determined delay (DRP) after ventricular activity (QRS), said circuitry detecting and range gating characteristic pulsed wave Doppler waveform (151, 153, 154) produced by the blood flow through the tricuspid cardiac valve (125) or, if the lead form claim 4 has two transducers, detecting characteristic continuous wave Doppler waveform in the same area.

12. Device according to claim 11, comprising means for discrimination between early diastolic filling wave (151) and atrial filling wave (153), as well as means for measurement of peak velocities (E, A) of both waves and calculation of time integrals of both waves.

13. Device according to claim 12, comprising means for ventricular pacing (I) synchronous with atrial filling wave (154) detected by said circuitry, whereby ventricular pacing maintains the physiologic atrio-ventricular delay (155).

14. Device according to claim 12 or 13, comprising means (160 to 163, 168, 169) for calculation of ratio of the peak velocities (E/A) of said filling wave and calculation of ratio of the time integrals of said filling waves.

15. Device according to claim 14, comprising means (160, 161) for beat to beat comparison of said ratios, and means for detection of consecutive decrease of said ratios indicating the high rate induced ischemia, as well as means (160, 161) for successive decrease of ventricular pacing rate in the case of high rate ischemia in such a way as to prevent the high rate induced cardiac ischemia.

16. Device according to any of claims 10 to 15 comprising means (160, 161, 167) for detection of atrial fibrillation i.e. the disappearance of said atrial filling wave as well as means (160, 161, 166) to maintain the rate responsive ventricular pacing while the atrial fibrillation is sustained, and means (160, 161, 166) to revert to synchronous ventricular pacing upon the occurrence of said atrial filling wave.

17. Device according to any of claims 12 to 16, comprising means (counter "RR" in 160) for measurement of the time interval between the ventricular pacing impulse and the said early diastolic wave, said interval QE being the sensor for rate-responsive pacing in such a way that the pacing rate increases whenever the said interval QE decreases and vice versa.

18. Device according to any of claims 12 to 17, comprising means for detection of missing ventricular contractions i.e. the disappearance of said early diastolic waves (151), and means to discriminate if the missing contractions are caused by the loss of capture or by the ventricular fibrillation or tachycardia.

19. Device according to any of claims 12 to 18, comprising means for detection of sudden decrease of said measured peak velocity (E) of the said early diastolic wave (151) in single beat, said sudden decrease indicating that said single beat is the ventricular premature beat.

20. Device according to any of claims 12 to 16, comprising means for rate responsive pacing in such a way as to monitor the peak velocity (E) of the early ventricular filling wave (151) and to increase the pacing rate whenever the velocity (E) increases and vice versa.

21. Device according to any of claims 12 to 16, comprising means for rate responsive pacing in such a way as to measure the diastolic filling period as well as the rapid filling period and to increase the pacing rate whenever the said periods decrease and vice versa.

22. Device according to any of claims 12 to 16, comprising means for rate responsive pacing

in such a way as to measure and calculate the rapid filling fraction and to increase the pacing frequency whenever the said fraction decreases and vice versa.

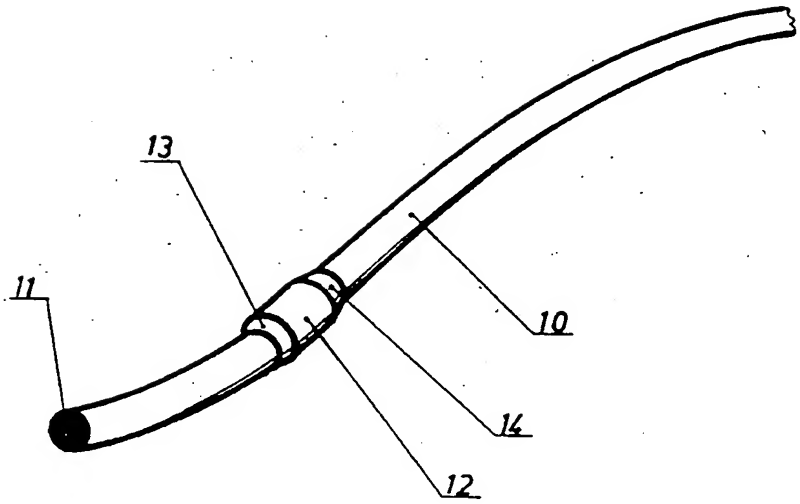


FIG.1

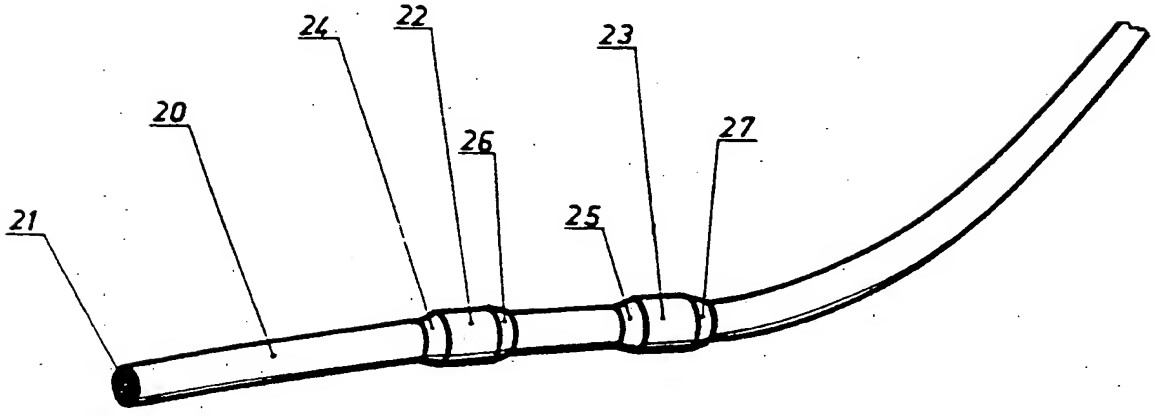


FIG. 2

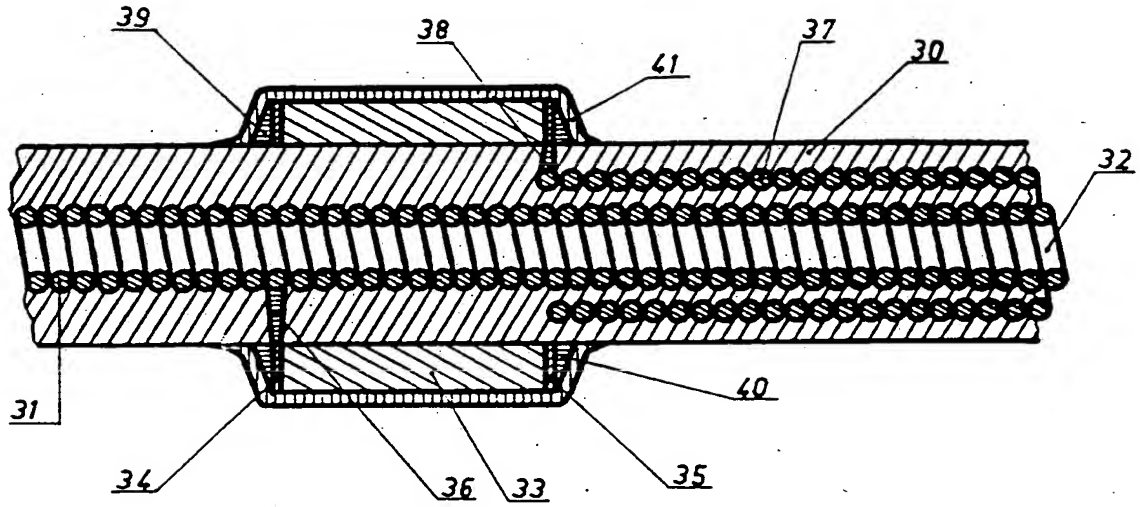

39
38
41
37
30
32
31
40
34
36
33
35

FIG. 3

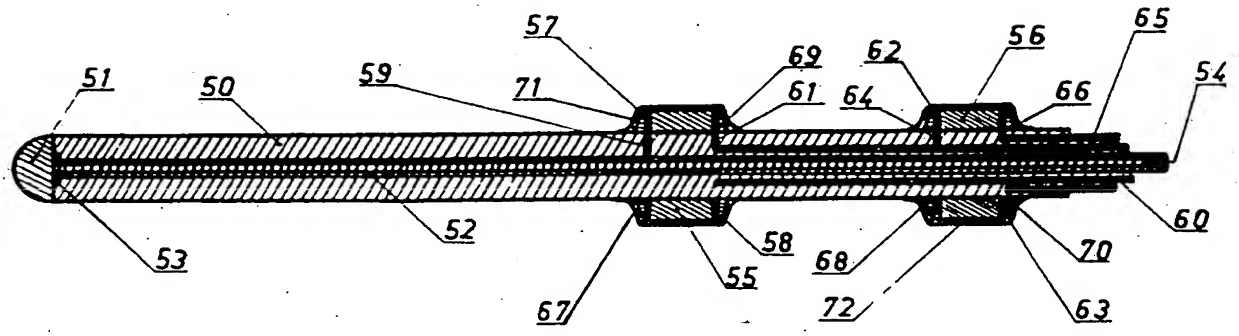

57
69
62
56
65
51
50
59
71
61
64
66
54
53
52
58
68
70
60
55
67
72
63

FIG. 4

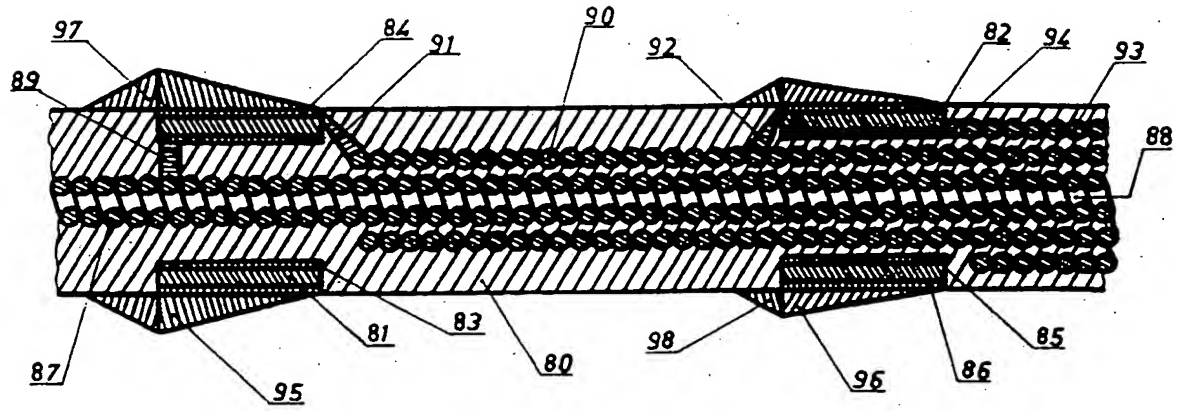

97
84
91
90
92
82
94
93
89
88
81
83
80
98
85
87
95
96
86

FIG. 5

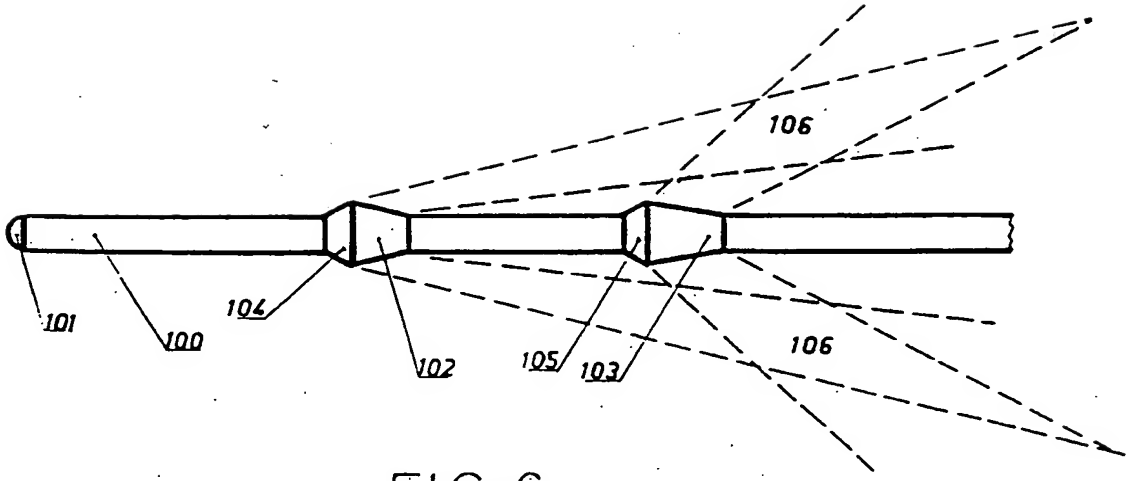

106
101
100
104
102
105
103
106

FIG. 6

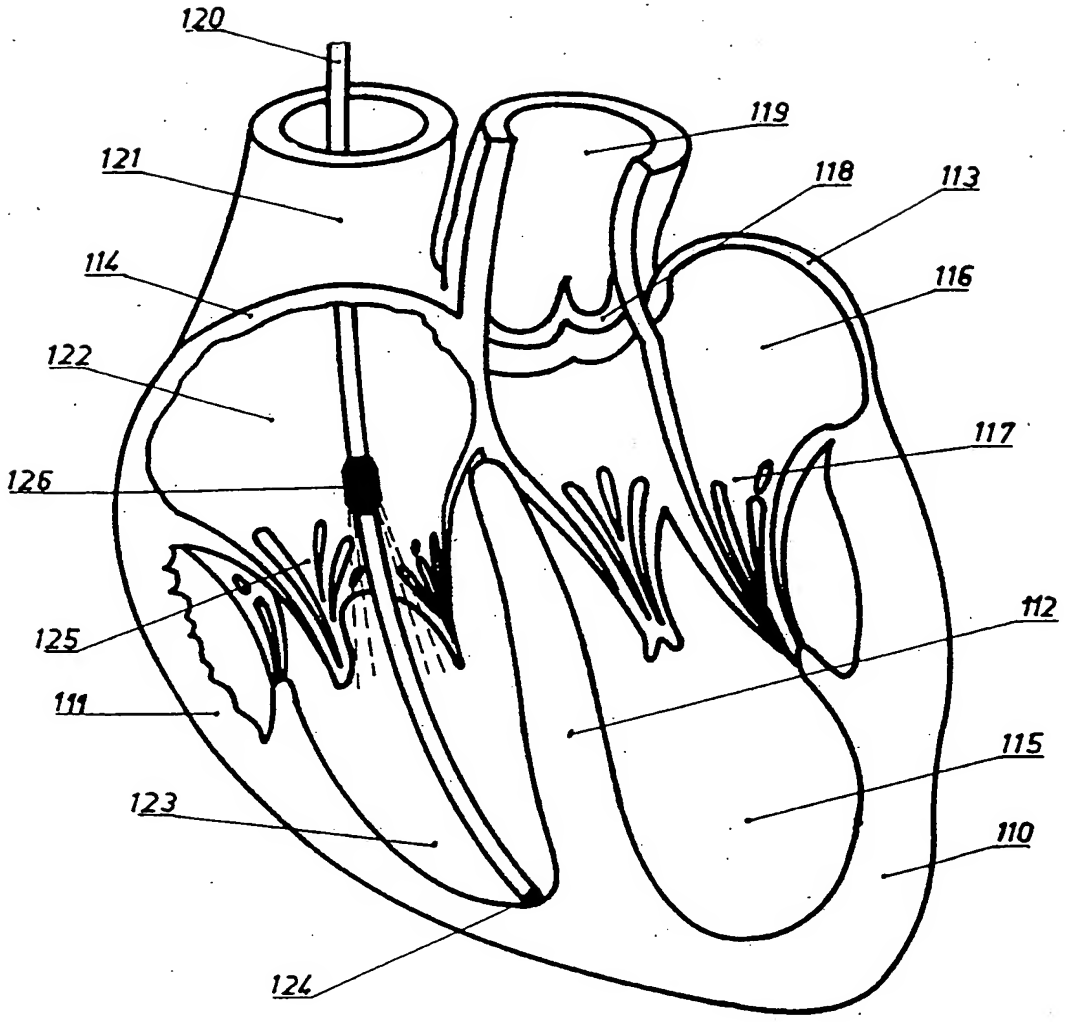

120
119
121
118
113
114
116
122
117
126
112
125
111
115
123
110
124

FIG. 7

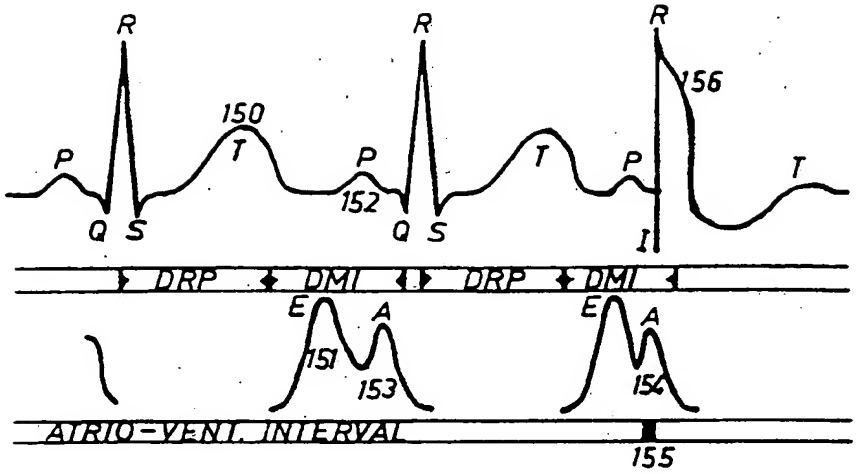

R
R
R
156
150
P
T
P
T
P
T
152
Q S
Q S
I
DRP
DMI
DRP
DMI
E
A
E
A
151
153
154
ATRIO-VENT. INTERVAL
155

FIG. 8

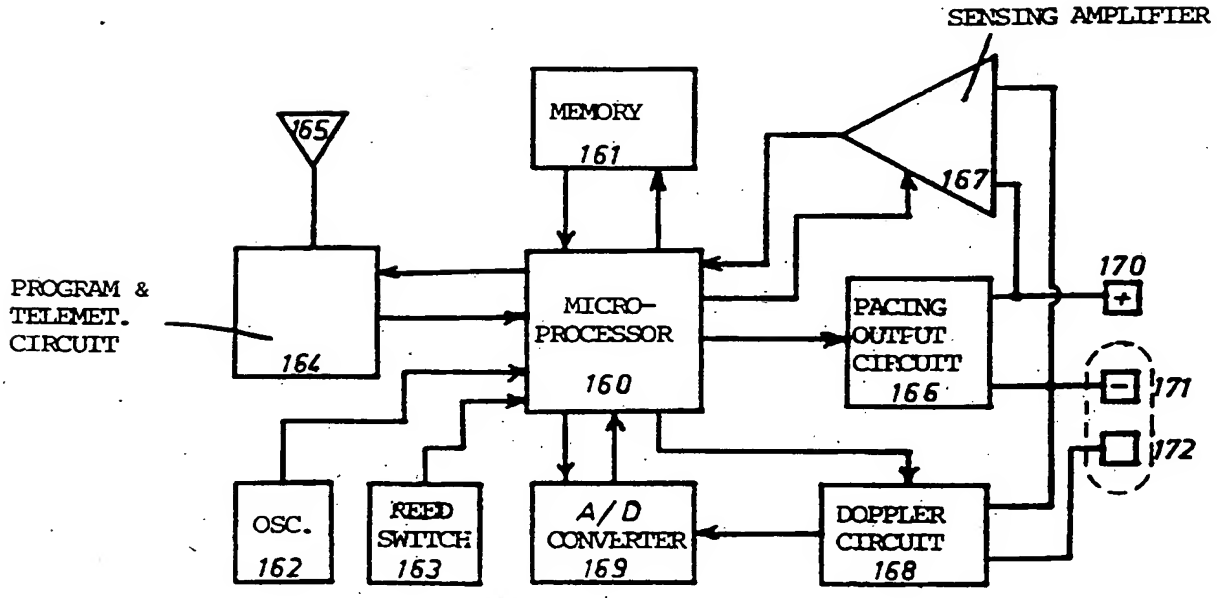

SENSING AMPLIFIER
MEMORY
161
165
167
PROGRAM &
TELEMET.
CIRCUIT
164
MICRO-
PROCESSOR
160
PACING
OUTPUT
CIRCUIT
166
170
171
172
OSC.
162
REED
SWITCH
163
A/D
CONVERTER
169
DOPPLER
CIRCUIT
168

FIG. 9

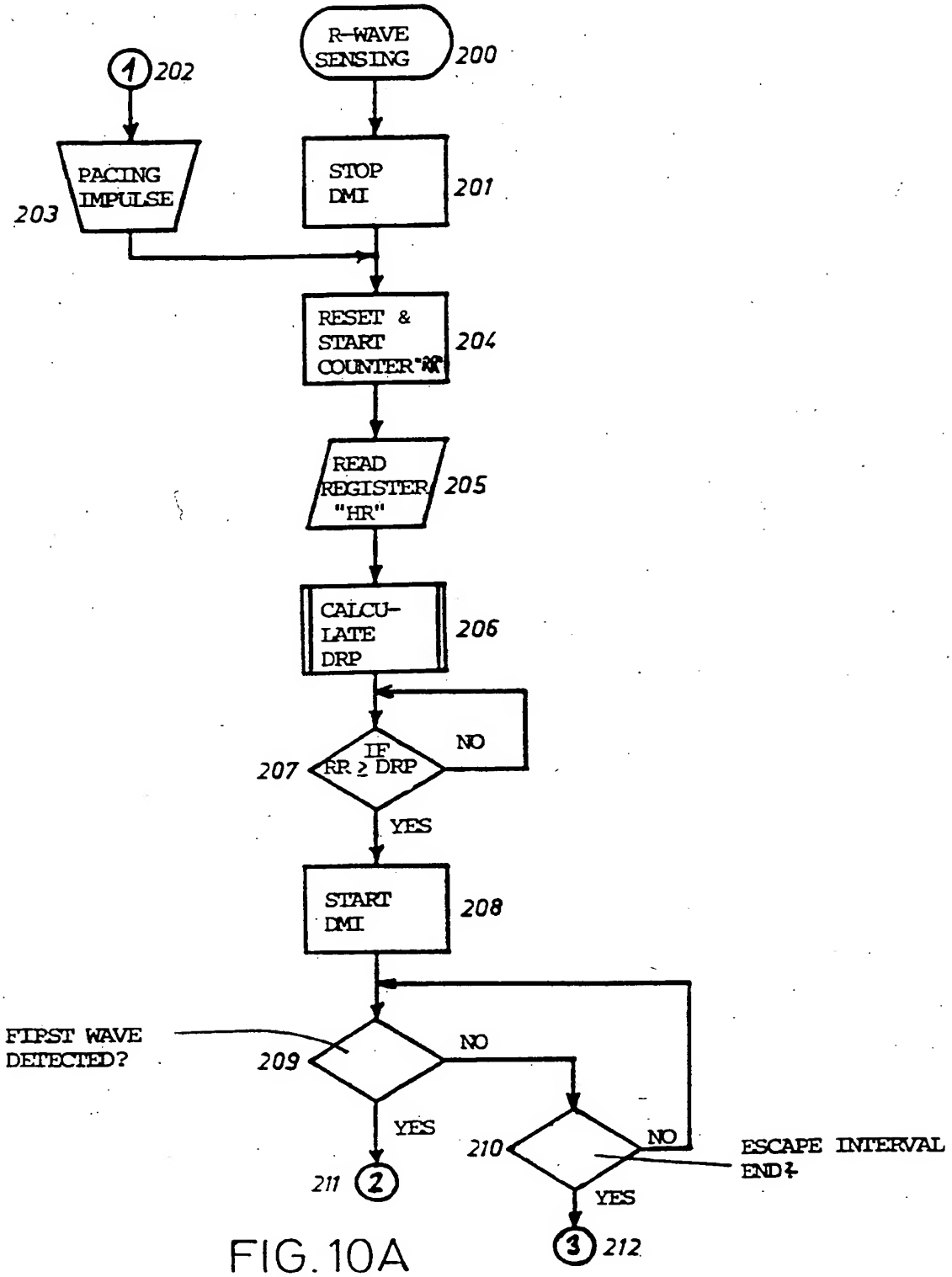

R-WAVE SENSING
200
1
202
PACING IMPULSE
203
STOP DMI
201
RESET & START COUNTER "R"
204
READ REGISTER "HR"
205
CALCU-LATE DRP
206
IF RR ≥ DRP
207
NO
YES
START DMI
208
FIRST WAVE DETECTED?
209
NO
YES
210
NO
ESCAPE INTERVAL END?
YES
211
2
3
212

FIG. 10A

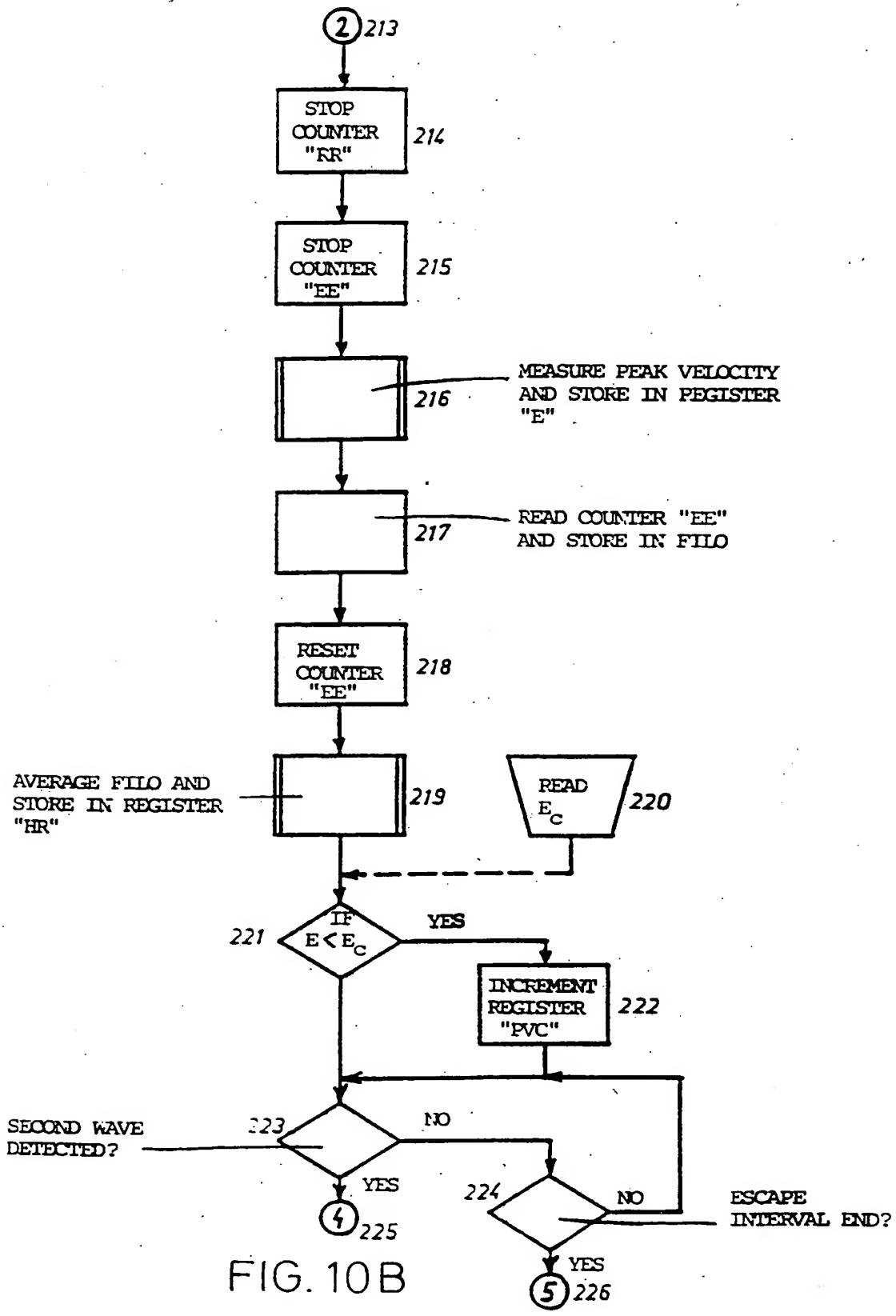

2
213
STOP COUNTER "RR"
214
STOP COUNTER "EE"
215
216
MEASURE PEAK VELOCITY AND STORE IN REGISTER "E"
217
READ COUNTER "EE" AND STORE IN FILO
RESET COUNTER "EE"
218
AVERAGE FILO AND STORE IN REGISTER "HR"
219
READ E_C
220
IF $E < E_C$
221
YES
INCREMENT REGISTER "PVC"
222
SECOND WAVE DETECTED?
223
NO
YES
4
225
224
NO
ESCAPE INTERVAL END?
YES
5
226

FIG. 10B

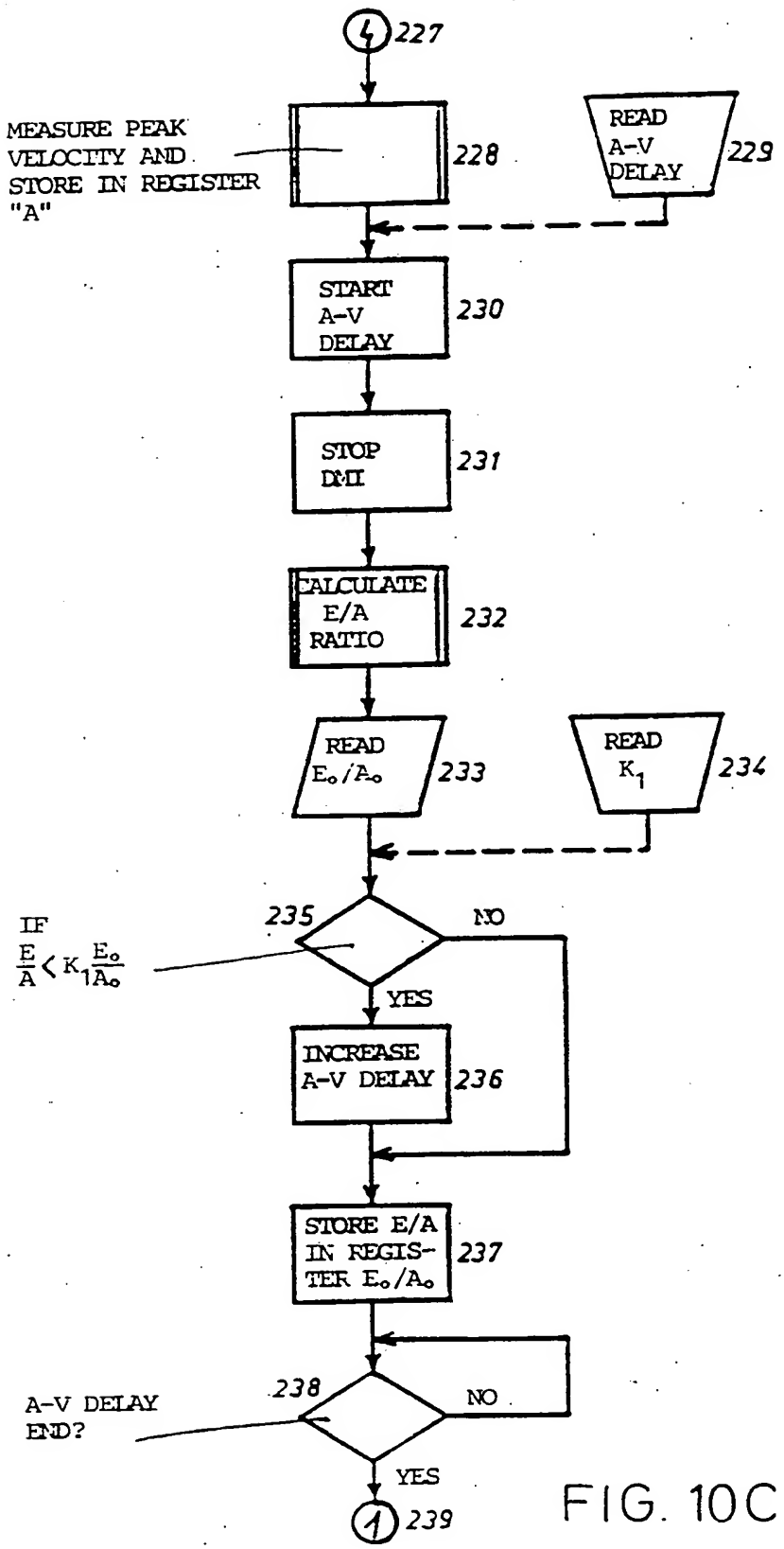

4
227
MEASURE PEAK VELOCITY AND STORE IN REGISTER "A"
228
READ A-V DELAY
229
START A-V DELAY
230
STOP DMI
231
CALCULATE E/A RATIO
232
READ E_o/A_o
233
READ K_1
234
IF $\frac{E}{A} < K_1 \frac{E_o}{A_o}$
235
NO
YES
INCREASE A-V DELAY
236
STORE E/A IN REGISTER E_o/A_o
237
A-V DELAY END?
238
NO
YES
1
239

FIG. 10C

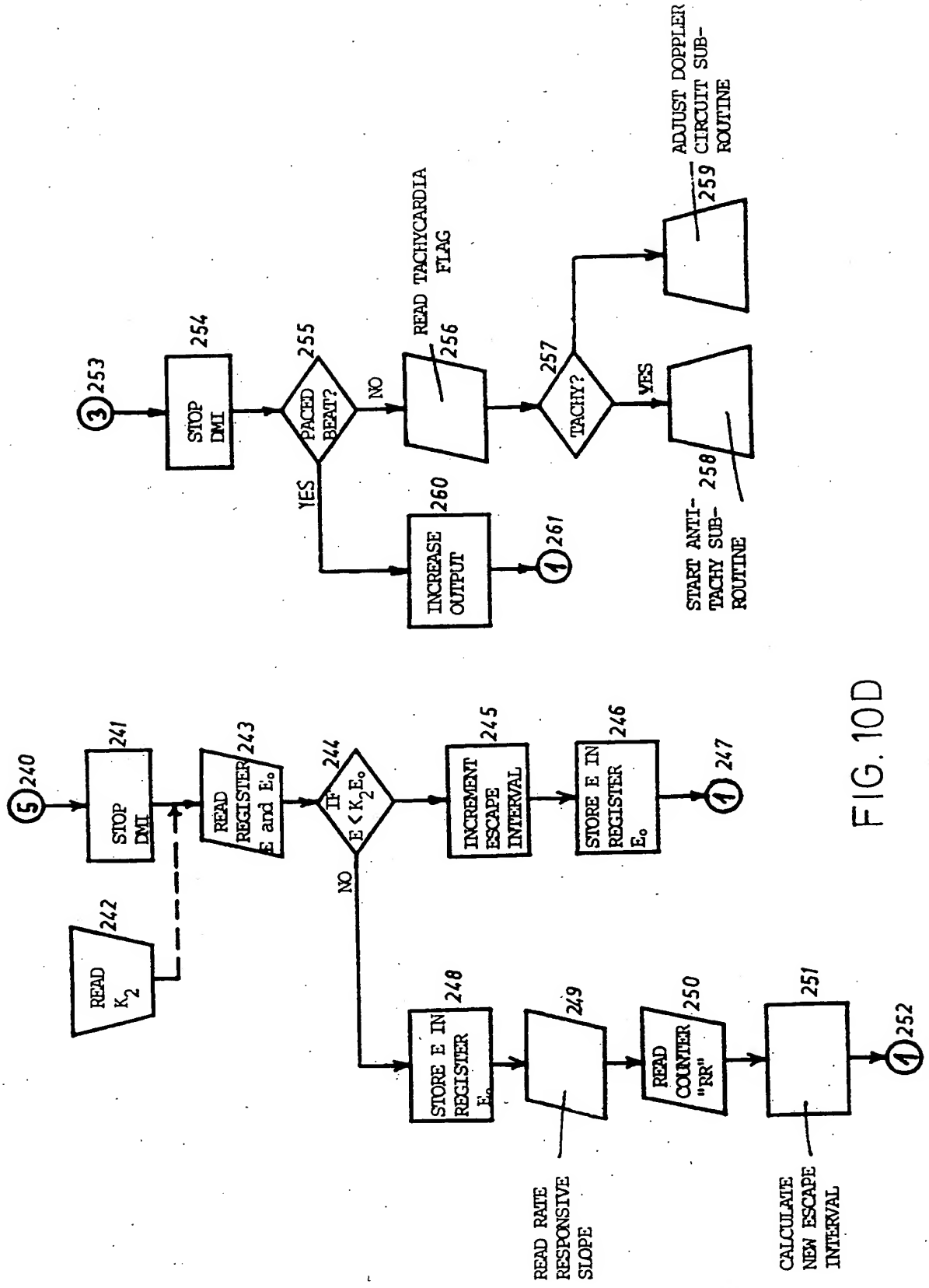

5 240
241
STOP DMI
242
READ K_2
243
READ REGISTER E and E_o
244
IF $E < K_2E_o$
NO
245
INCREMENT ESCAPE INTERVAL
246
STORE E IN REGISTER E_o
247
1
248
STORE E IN REGISTER E_o
249
READ RATE RESPONSIVE SLOPE
250
READ COUNTER "RR"
251
CALCULATE NEW ESCAPE INTERVAL
252
1
3 253
254
STOP DMI
255
PACED BEAT?
YES
NO
256
READ TACHYCARDIA FLAG
257
TACHY?
YES
NO
258
START ANTI-TACHY SUB-ROUTINE
259
ADJUST DOPPLER CIRCUIT SUB-ROUTINE
260
INCREASE OUTPUT
261
1

FIG. 10D

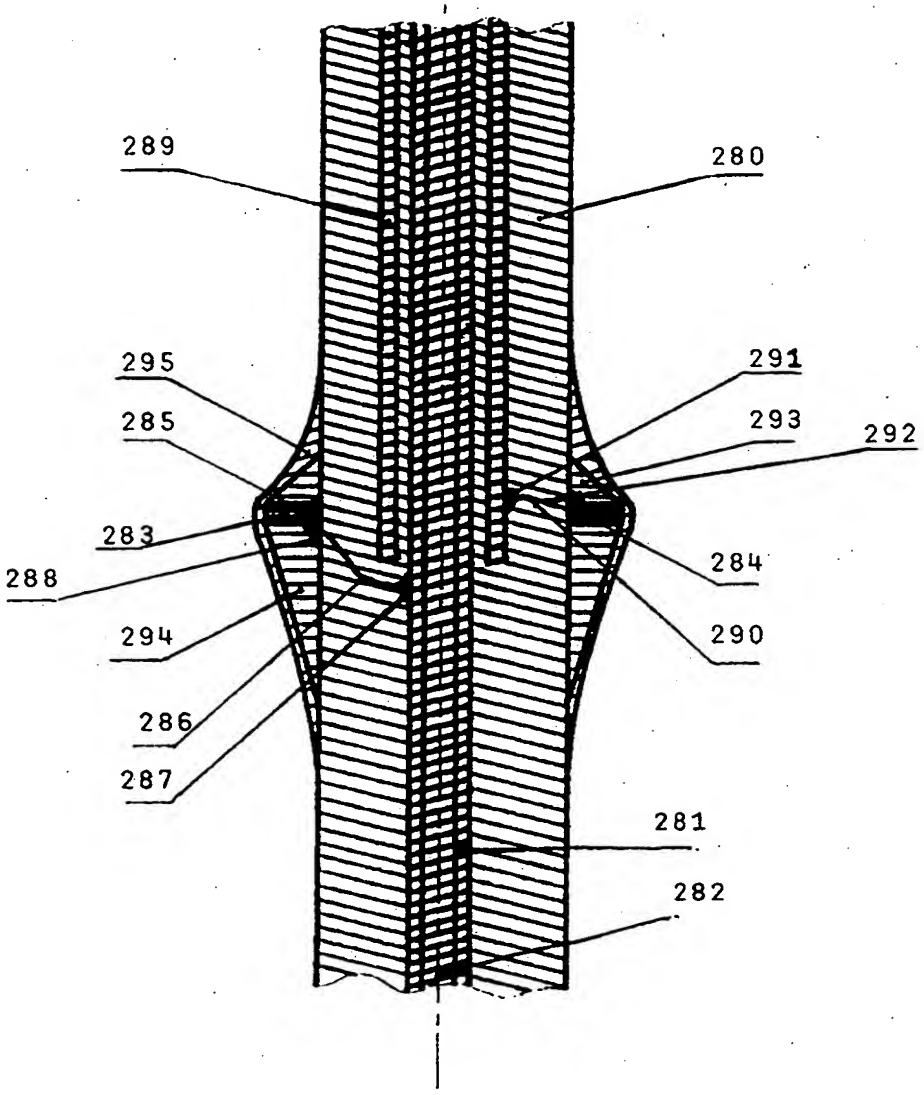


FIG. 11

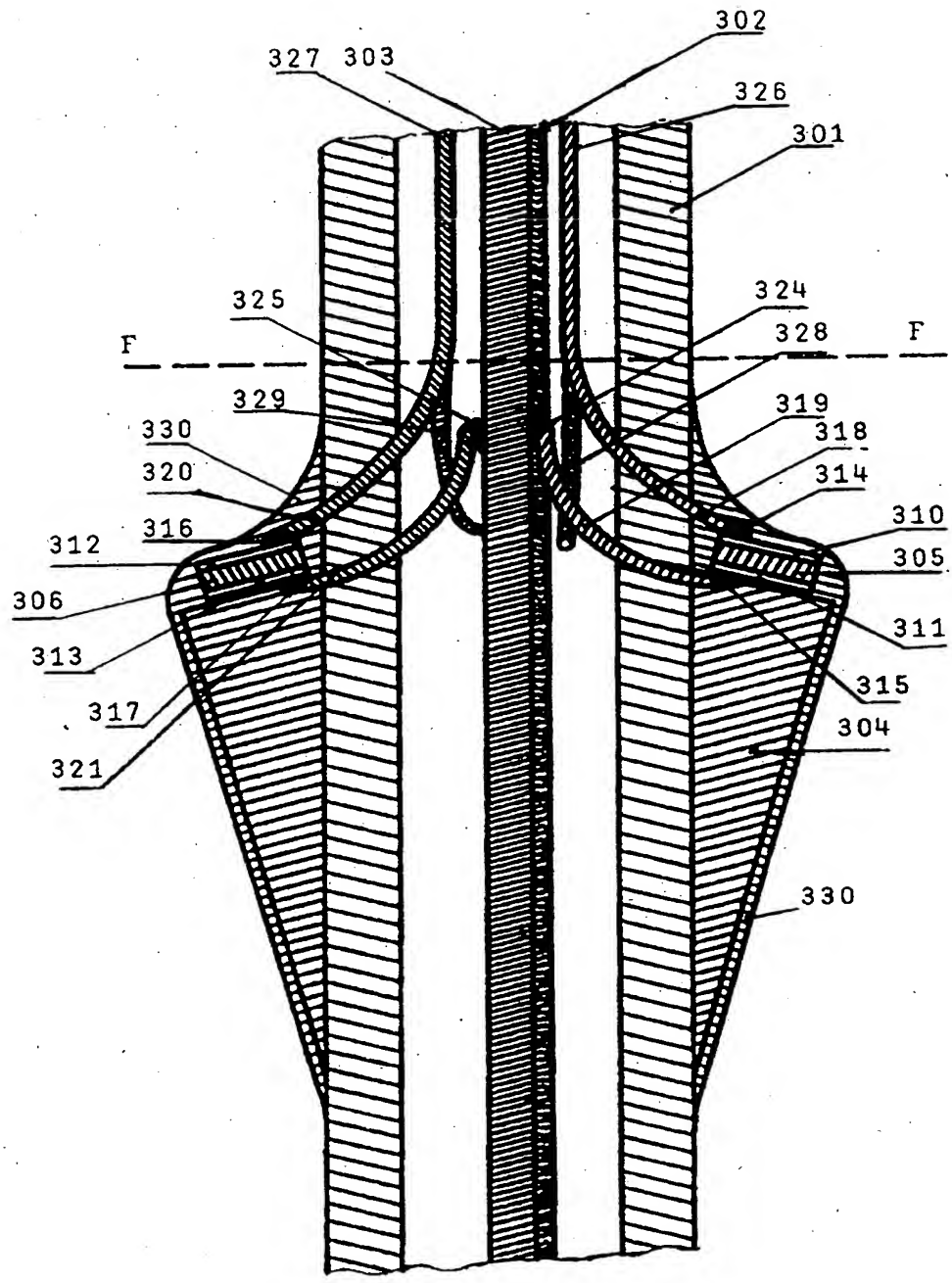
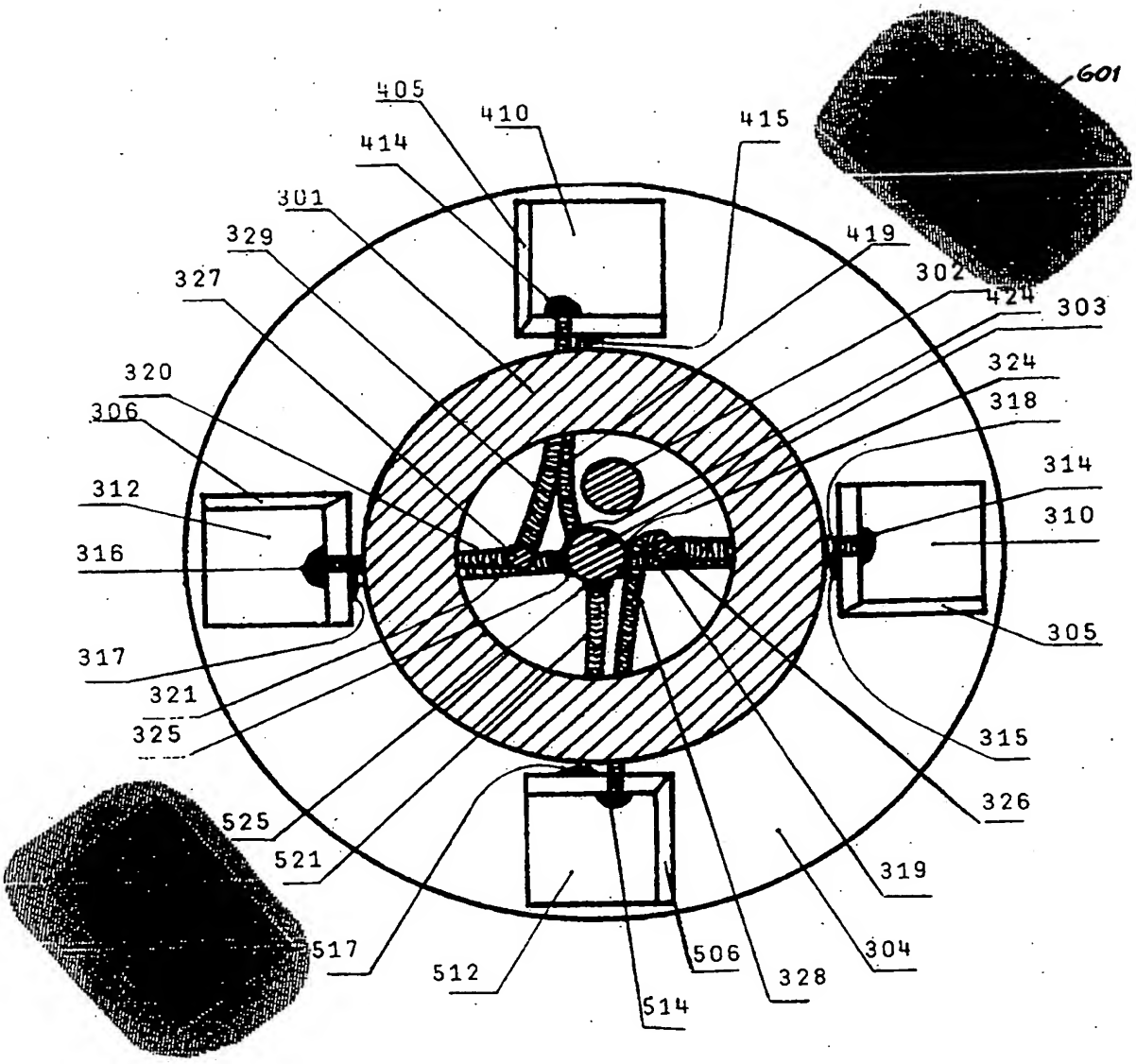

302
327
303
326
301
325
324
F
328
F
329
319
330
318
320
314
316
310
312
305
306
311
313
315
317
304
321
330

FIG. 12


601
405
410
415
414
301
329
327
419
302
424
303
320
306
324
318
312
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316
310
317
305
321
315
325
326
525
521
319
517
512
506
328
304
514

FIG. 13

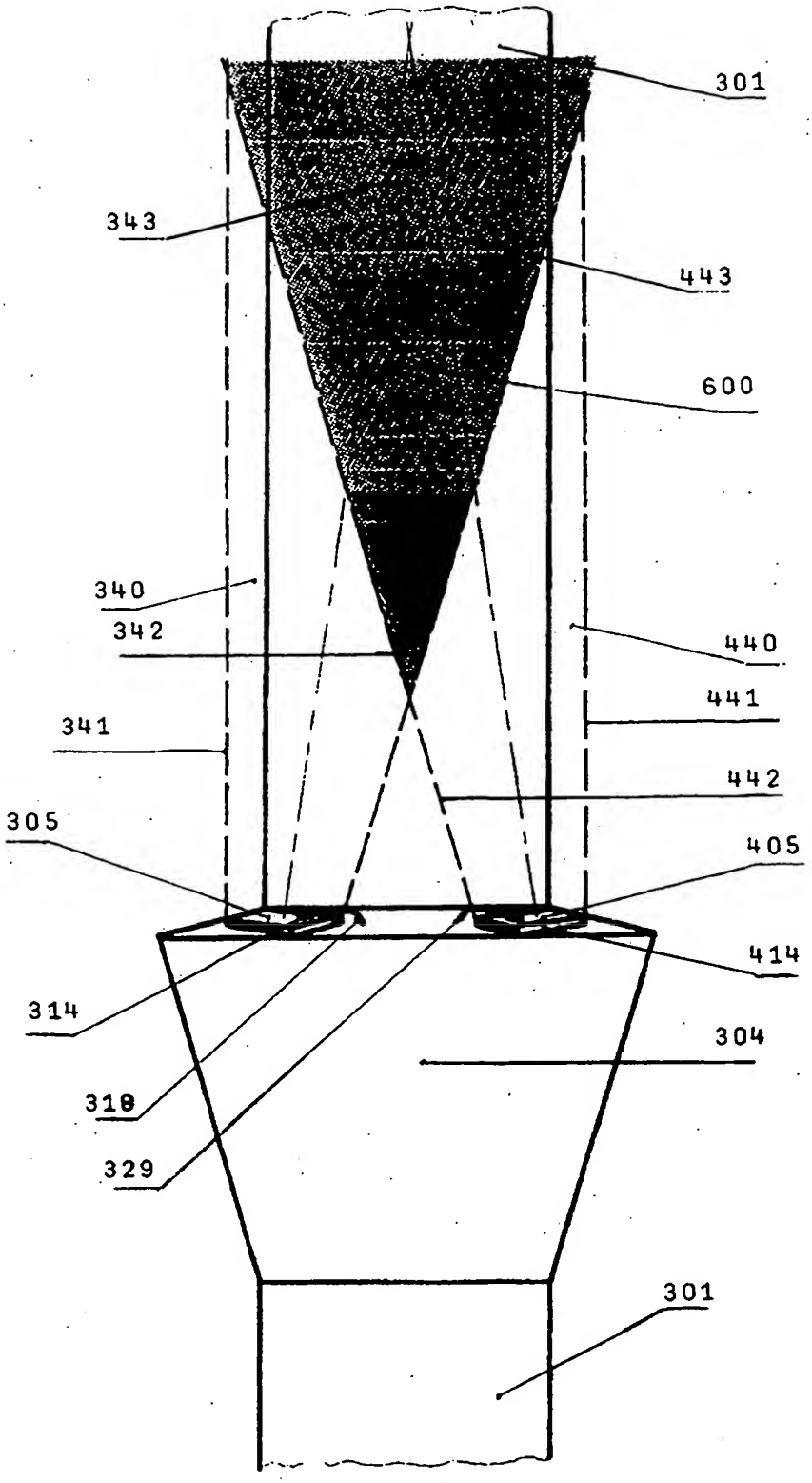
301
343
443
600
340
342
440
441
341
442
305
405
414
314
304
318
329
301

FIG. 14

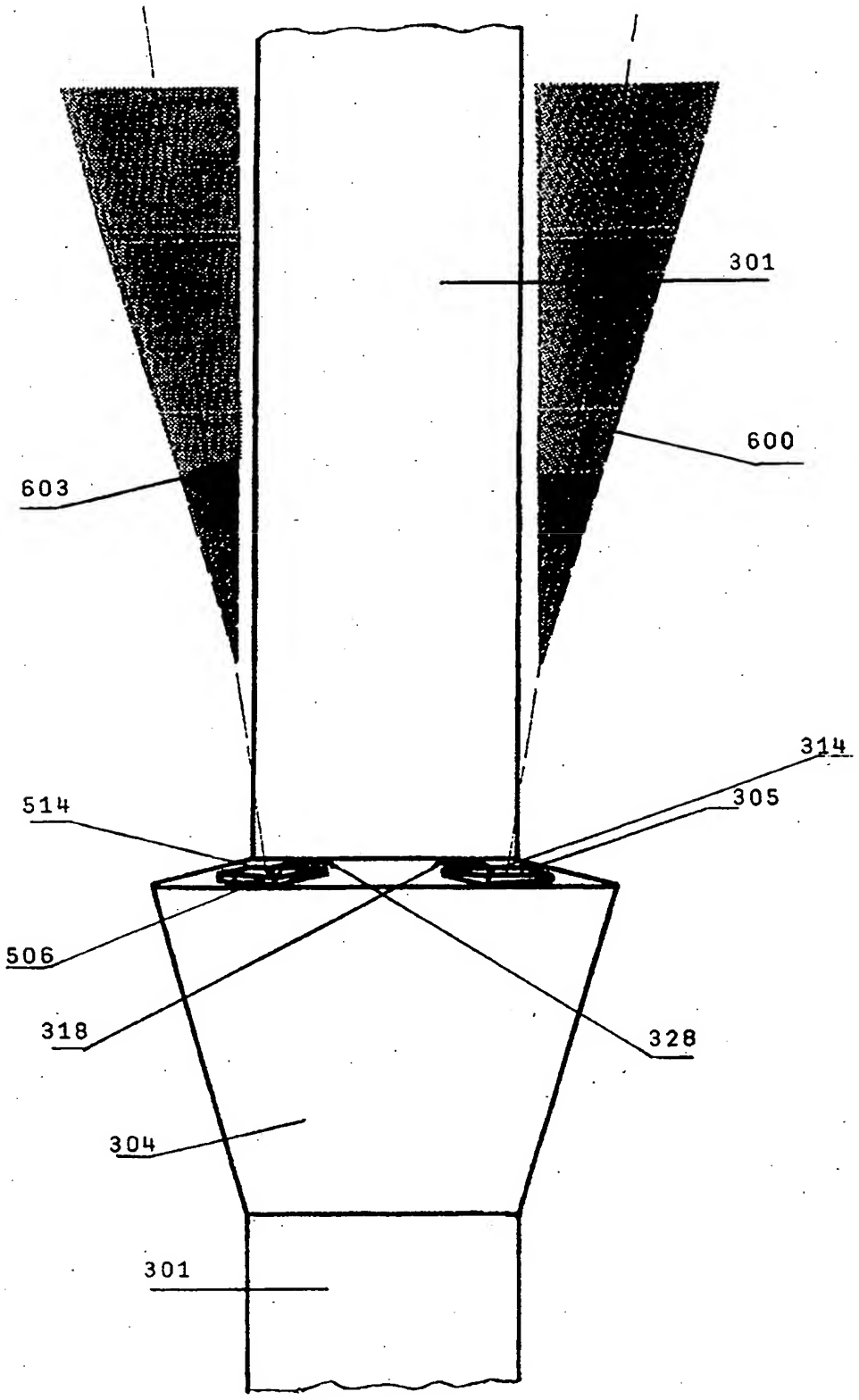

FIG. 15